

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department seeking assistance and includes a physician on call for the care of such individual.

Secretary means the Secretary of the Department or his or her designees.

Select agents and toxins means agents and toxins that are listed by the HHS Secretary as having the potential to pose a severe threat to public health and safety, in accordance with section 351A(a)(1) of the Public Health Service Act.

Should know or should have known means that a person, with respect to information—

- (1) Acts in deliberate ignorance of the truth or falsity of the information; or
- (2) Acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

Timely basis means, in accordance with § 1003.102(b)(9) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

Transitional assistance means the subsidy funds that Medicare beneficiaries enrolled in the prescription drug discount card and transitional assistance program may apply toward the cost of covered discount card drugs in the

manner described in § 403.808(d) of this title.

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§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has knowingly presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that is part of a pattern or practice of claims based on codes that the person knows or should know will result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent, including a claim for any item or service furnished by an excluded individual employed by or otherwise under contract with that person;

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was made;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

- (i) Was not licensed as a physician;
- (ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or
- (iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified;

(5) A payment that such person knows, or should know, may not be made under § 411.353 of this title; or

(6) An item or service that a person knows or should know is medically unnecessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(1) Has knowingly presented or caused to be presented a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act.

(2)–(3) [Reserved]

(4) Has knowingly given or caused to be given to any person, in the case of inpatient hospital services subject to the provisions of section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital.

(5) Fails to report information concerning—

(i) A payment made under an insurance policy, self-insurance or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist or other practitioner in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60; or

(ii) An adverse action required to be reported to the Healthcare Integrity and Protection Data Bank as estab-

lished by section 221 of Public Law 104–191 and set forth in section 1128E of the Act.

(6) Improperly discloses, uses or permits access to information reported in accordance with part B of title IV of Pub. L. 99–660, in violation of section 427 of Pub. L. 99–660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with part B of title IV in response to a subpoena or a discovery request is considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660.)

(7) Has made use of the words, letters, symbols or emblems as defined in paragraph (b)(7)(i) of this section in such a manner that such person knew or should have known would convey, or in a manner which reasonably could be interpreted or construed as conveying, the false impression that an advertisement, solicitation or other item was authorized, approved or endorsed by the Department or CMS, or that such person or organization has some connection with or authorization from the Department or CMS. Civil money penalties—

(i) May be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department or its programs, for misuse of—

(A) The words “Department of Health and Human Services,” “Health and Human Services,” “Centers for Medicare & Medicaid Services,” “Medicare,” or “Medicaid,” or any other combination or variation of such words;

(B) The letters “DHHS,” “HHS,” or “CMS,” or any other combination or variation of such letters; or

(C) A symbol or emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under title II, or envelopes or other stationery used by the Department or

CMS) or any other combination or variation of such symbols or emblems; and

(ii) Will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that makes use of any symbol or emblem, or any words or letters which specifically identifies that agency or instrumentality of the State or political subdivision.

(8) Is a contracting organization that CMS determines has committed an act or failed to comply with the requirements set forth in §417.500(a) or §434.67(a) of this title or failed to comply with the requirement set forth in §434.80(c) of this title.

(9) Has not refunded on a timely basis, as defined in §1003.101 of this part, amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in §411.353 of this title.

(10) Is a physician or entity that enters into—

(i) A cross referral arrangement, for example, whereby the physician owners of entity “X” refer to entity “Y,” and the physician owners of entity “Y” refer to entity “X” in violation of §411.353 of this title, or

(ii) Any other arrangement or scheme that the physician or entity knows, or should know, has a principal purpose of circumventing the prohibitions of §411.353 of this title.

(11) Has violated section 1128B of the Act by unlawfully offering, paying, soliciting or receiving remuneration in return for the referral of business paid for by Medicare, Medicaid or other Federal health care programs.

(12) Who is not an organization, agency or other entity, and who is excluded from participating in Medicare or a State health care program in accordance with sections 1128 or 1128A of the Act, and who—

(i) Knows or should know of the action constituting the basis for the exclusion, and retains a direct or indirect ownership or control interest of five percent or more in an entity that participates in Medicare or a State health care program; or

(ii) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such entity.

(13) Offers or transfers remuneration (as defined in §1003.101 of this part) to any individual eligible for benefits under Medicare or a State health care program, that such person knows or should know is likely to influence such individual to order or to receive from a particular provider, practitioner or supplier any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(14) Is a physician and who executes a document falsely by certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements set forth in sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(15) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under the Medicare or another Federal health care program, if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act, or violates the requirements for such an arrangement.

(16) Is involved in the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins in violation of part 73 of this chapter as determined by the HHS Secretary, in accordance with sections 351A(b) and (c) of the Public Health Service Act.

(17) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly misrepresented or falsified information in outreach material or comparable material provided to a program enrollee or other person.

(18) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly charged a program enrollee in violation of the terms of the endorsement contract.

(19) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly used transitional assistance funds of any

program enrollee in any manner that is inconsistent with the purpose of the transitional assistance program.

(c)(1) The Office of the Inspector General (OIG) may impose a penalty for violations of section 1867 of the Act or § 489.24 of this title against—

(i) Any participating hospital with an emergency department that—

(A) Knowingly violates the statute on or after August 1, 1986 or;

(B) Negligently violates the statute on or after May 1, 1991; and

(ii) Any responsible physician who—

(A) Knowingly violates the statute on or after August 1, 1986;

(B) Negligently violates the statute on or after May 1, 1991;

(C) Signs a certification under section 1867(c)(1)(A) of the Act if the physician knew or should have known that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(D) Misrepresents an individual's condition or other information, including a hospital's obligations under this section.

(2) For purposes of this section, a responsible physician or hospital “knowingly” violates section 1867 of the Act if the responsible physician or hospital recklessly disregards, or deliberately ignores a material fact.

(d)(1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(2) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a request for payment or for giving false or misleading information as described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

(3) In any case in which it is determined that more than one person was

responsible for failing to report information that is required to be reported on a medical malpractice payment, or for improperly disclosing, using, or permitting access to information, as described in paragraphs (b)(5) and (b)(6) of this section, each such person may be held liable for the penalty prescribed by this part.

(4) In any case in which it is determined that more than one responsible physician violated the provisions of section 1867 of the Act or of § 489.24 of this title, a penalty may be imposed against each responsible physician.

(5) Under this section, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(e) For purposes of this section, the term “knowingly” is defined consistent with the definition set forth in the Civil False Claims Act (31 U.S.C. 3729(b)), that is, a person, with respect to information, has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required.

[57 FR 3345, Jan. 29, 1992; 57 FR 9670, Mar. 20, 1992, as amended at 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 64 FR 39428, July 22, 1999; 65 FR 18550, Apr. 7, 2000; 65 FR 24415, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) through (k) of this section, the OIG may impose a penalty of not more than—

(1) \$2,000 for each wrongful act occurring before January 1, 1997 that is subject to a determination under § 1003.102; and

(2) \$10,000 for each wrongful act occurring on or after January 1, 1997 that is subject to a determination under § 1003.102.

(b) The OIG may impose a penalty of not more than \$15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.102(b)(4), or for each item and